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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/034,292	01/03/2002	Florrye Cleveland	D6338CIP	9506

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EXAMINER

JOHANNSEN, DIANA B

ART UNIT PAPER NUMBER

1634

DATE MAILED: 08/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/034,292	CLEVELAND ET AL.	
	Examiner	Art Unit	
	Diana B. Johannsen	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 May 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15 and 16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: |

FINAL REJECTION

1. This action is in response to the Amendment and Response filed May 22, 2003. Claims 1-14 and 17-20 have been canceled, and claims 15-16 have been amended. Claims 15-16 are now pending and under consideration. The amendments and arguments have been thoroughly reviewed, but are not persuasive for the reasons that follow. Any rejections not reiterated in this action have been withdrawn as being obviated by the amendment of the claims. **This action is FINAL.**
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Priority

3. It is noted that a petition to revive (for purposes of continuity) was granted in parent application 09/260,743 on February 20, 2003. However, as multiple features of the claimed invention were not disclosed in the '743 application (e.g., a storage card comprising "one or more specimen circles," a step of blotting "onto a specimen circle"), the effective filing date of the instant application remains **January 3, 2002**.

Oath/Declaration

4. It is noted that a new declaration was filed with Applicants' response on May 22, 2003. However, the new declaration is also defective because it claims benefit under **35 U.S.C. 119(e)** to a non-provisional application (US application no. 09/260,743). A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

Claim Rejections - 35 USC § 112

**THE FOLLOWING ARE NEW GROUNDS OF REJECTION NECESSITATED BY
APPLICANTS AMENDMENTS TO THE CLAIMS:**

5. Claim 16 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 16 is indefinite because while the claim requires "repeating steps (a) to (c) until all of the specimen circles on said storage card contain a non-blood sample affixed thereto," claim 15 (from which claim 16 depends) merely requires a storage card comprising "one or more specimen circles." It is unclear as to whether and how claim 16 further limits claim 15 to the extent that the claim is drawn to a card comprising one specimen circle (i.e., how would the step of "repeating steps (a) to (c)" be practiced with a storage card having only 1 specimen circle?). This rejection could be overcome by amending claim 16 to recite, e.g., "The method of claim 15, wherein said storage card comprises multiple specimen circles, and wherein the method further comprises repeating steps (a) to (c).....".

Claim Rejections - 35 USC § 102

6. In view of the cancellation of claims 17-19, the rejection of those claims as being anticipated by Quattrocchi is moot.

7. In view of the cancellation of claim 20, the rejection of the claim as being anticipated by Quattrocchi, in light of the teachings of Roget and the teachings of Turner, is moot.

Claim Rejections - 35 USC § 103

8. In view of the cancellation of claims 1-14 and 17-20, the following rejections under 35 U.S.C. 103(a) are moot:

- a) the rejection of claims 1-6 and 14 as being unpatentable over Burgoyne in view of Quattrocchi;
- b) the rejection of claim 13 as being unpatentable over Burgoyne in view of Quattrocchi, and further in view of Roget;
- c) the rejection of claims 7-9 as being unpatentable over Burgoyne in view of Quattrocchi, and further in view of Tess et al;
- d) the rejection of claims 10-12 as being unpatentable over Burgoyne in view of Quattrocchi, and further in view of Haas et al;
- e) the rejection of claim 13 as being unpatentable over Burgoyne in view of Quattrocchi, and further in view of Biddle et al; and
- f) the rejection of claims 17-20 as being unpatentable over Burgoyne in view of Quattrocchi and Tess et al, and further in view of Haas et al and Biddle et al.

9. Claims 15-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burgoyne in view of Quattrocchi and Tess et al, and further in view of Haas et al, in light of Roget, for the reasons set forth in the Office action of February 13, 2003.

The response traverses the rejection on the following grounds. The response argues that it would not have been obvious to have modified the method of Burgoyne and Quattrocchi "so as to collect oral fluid samples using a sponge." The response states that "Tess et al do not teach or suggest swabbing the inside of the mouth to obtain a non-blood sample for genetic analysis as claimed herein" and that "Tess et al only teach collecting salivary samples to detect anti-HIV antibodies." The response urges that "Tess et al do not teach or suggest collecting salivary samples for DNA or RNA analysis," and that Tess et al do not provide motivation "to combine with Burgoyne and Quattrocchi so as to collect non-blood samples for DNA analysis as claimed herein"

and further do not "provide any reasonable expectation of success in obtaining salivary samples for DNA analysis." The response further argues that Tess et al "only teach rubbing a soft sponge foam swab along the junction of the teeth and gums for 1 minute so as to saturate the sponge with saliva," and that "Swabbing the inside of the mouth is clearly distinguishable from rubbing on the gums for one minute because one of ordinary skill in the art would readily realize that rubbing and soaking for one minute is not swabbing." Applicants contend that "One of skill in the art would readily comprehend swabbing in the context of collecting oral samples as a quick and brief procedure that does not entail rubbing and soaking with saliva for at least 1 minute."

Applicants' arguments have been thoroughly considered but are not persuasive. First, with respect to Applicants' arguments regarding a requirement for samples "for DNA analysis," it is noted that the instant claims do not recite DNA and/or RNA analysis, but rather refer to a sample "for genetic analysis." Similarly, while Applicants argue that the invention requires only "a brief step of swabbing" (suggesting that the procedure of Tess et al takes too long to meet the claims), it is noted that the claims do not include any time limitation on the act of swabbing. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The instant claims require a step of "swabbing the inside of the mouth of said subject with a sponge to obtain a non-blood sample comprising mouth cells." The claims include no limitations as to the location within the mouth that is to be swabbed, the type of motion that must be employed to accomplish "swabbing", and/or as to the duration of swabbing. Further,

the specification does not include any kind of definition of the term "swabbing" that would limit this terminology in a way that would exclude the type of swabbing to achieve sample collection that is taught by Tess et al. Accordingly, as the procedure taught by Tess et al, which requires rubbing a sponge foam swab along the crevicular space, is a type of swabbing which results in the collection of a non-blood sample comprising "mouth cells," the procedure of Tess et al clearly meets the requirements of the claims as written. Regarding Applicants' argument that one of ordinary skill would not have been motivated to have collected samples using the method of Tess et al for use in the method suggested by Burgoyne and Quattrocchi, it is again noted that, as indicated in the Office action of February 13, 2003, Burgoyne teaches that samples of genetic material collected and stored on his media may be "derived from any source," may include saliva containing cells, and are to be collected by methods "known in the art" (col 4, lines 49-59; col 5, lines 5-20). Accordingly, as was stated in said Office action, given Tess et al's teachings regarding the benefits of their collection method, an ordinary artisan would have been motivated to have selected this collection method (as opposed to other methods "known in the art") for the advantage of providing a rapid, painless and familiar means of collecting samples from children, as suggested by the teachings of Tess et al. Additionally, given that the method of Tess et al requires rubbing of a sponge swab along the crevicular space for approximately 1 minute, an ordinary artisan would clearly have had a reasonable expectation of success in collecting sufficient mouth cells and material for subsequent "genetic analysis." The instant claims do not require collection of, e.g., a specific quantity of DNA and/or RNA

for use in a particular method, but rather encompass collection of a sample that contains any type of "mouth cells" that could be employed in any type of "genetic analysis." Accordingly, Applicants' arguments are not persuasive.

The combined references of Burgoyne, Quattrocchi, Tess et al, and Haas et al (in light of Roget) suggest all the limitations of present claims 15-16 and therefore this rejection is maintained.

10. Claims 15-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burgoyne in view of Quattrocchi and Tess et al, and further in view of Haas et al and Biddle et al, for the reasons set forth in the Office action of February 13, 2003.

The response traverses the rejection for the same reasons discussed in paragraph 9, above, regarding the Tess et al reference. Accordingly, the response to those arguments applies equally herein.

The combined references of Burgoyne, Quattrocchi, Tess et al, Haas et al, and Biddle et al suggest all the limitations of present claims 15-16 and therefore this rejection is maintained.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diana B. Johannsen whose telephone number is 703/305-0761. The examiner can normally be reached on Monday-Friday, 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached at 703/308-1152. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703/308-0196.



Diana B. Johannsen
August 19, 2003


CARLA J. MYERS
PRIMARY EXAMINER